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10/728,033	12/04/2003	Stephen F. Badylak	3220-73985	8358
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BARNES & THORNBURG LLP			SCHUBERG, LAURA J	
11 SOUTH MERIDIAN			ART UNIT	PAPER NUMBER
INDIANAPOLIS, IN 46204			1657	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/728,033	BADYLAK, STEPHEN F.
	Examiner	Art Unit
	Laura Schuberg	1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 12 March 2007.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Arguments***

Applicant's arguments filed 03/12/2007 have been fully considered but they are not persuasive.

Applicant argues that the graft compositions described in WO 98/25637 are not compositionally and structurally identical to those described in the '110 patent. Applicant asserts that it is accordingly not obvious that the liver-derived graft composition described in WO 98/25637 could be substituted for the compositions described in the '110 patent and could be used effectively for *in vivo* repair of a complex structure such as a body wall. Applicant asserts that Applicant's statement (from WO 98/25637) that liver basement membrane "can be substituted for intestinal submucosa tissue in most, if not all, of the applications previously reported for intestinal submucosa, including enhanced wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation" refer to general effects of liver basement membrane graft compositions. Applicant asserts that these statements do not mean that because liver basement membrane compositions cause growth-promoting effects it is obvious that they would be effective in repairing *in vivo* the complex structure of Applicant's amended claims 1-9.

This is not found persuasive because Patel (the '110 patent) specifically teaches that the submucosal tissue, suitable for use in the graft constructs used for repair of the abdominal body wall, comprises naturally associated extracellular matrix proteins, glycoproteins and other factors and that one source of this tissue is small intestinal

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tissue (column 3 lines 25-27). Clearly other types of tissue that are similar in structure and composition are to be considered as suitable as well. In addition, the WO document (WO 98/25637) teaches that the liver basement membrane construct can be further manipulated to suit various medical applications (page 9 lines 10-11), including *in vivo* repair (page 12 line 14). The WO document also reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20). Clearly it is not required that liver basement membrane be compositionally and structurally identical to those described in the '110 patent for it to be considered as a suitable substitute.

Applicant has correctly pointed out that the Examiner meant to reject the claims for obvious-type double patenting over co-pending 10/775,386, as well as patent 6,793,939. The Examiner is grateful for the correction and the subsequent addressing of the rejections as intended.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak (WO 98/25637) in view of Patel et al (US 5,955,110).

Claims 1, 3, 4, 6-9 are drawn to the method as described above.

Claim 2 is drawn to the method of claim 1 wherein the body wall tissue being repaired comprises the abdominal wall.

Claim 5 is drawn to the method of claim 4 wherein the graft composition is formed as a multilayered homolaminate construct.

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500  $\mu$  (page 17 line 14).

Badylak ('637) does not specifically teach wherein the body wall tissue to be repaired comprises the abdominal wall or wherein the graft composition is formed as a multilayered homolaminate construct.

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

In addition, Badylak ('637) teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since

the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, one of ordinary skill in the art would have been motivated to use the invention of Badylak ('637) for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20).

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badlak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus

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would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, the combined teachings of Badylak and Patel render obvious Applicant's invention as claimed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24 and 25 of copending Application No. 10/775,386 in view of Patel et al (US 5,955,110) and Badylak (WO 98/25637). Although the conflicting claims are not identical, they are not patentable distinct from each other because the copending application is drawn to a method for inducing the formation of endogenous tissue at a site in need in a warm-blooded vertebrate comprising implanting a graft composition comprising gelled liver basement membrane tissue of a warm-blooded vertebrate at the site in need in an amount effective and wherein the composition is implanted surgically.

The copending application does not include wherein the body wall or abdominal wall is the site of repair or wherein the construct is multilayered, the thickness of the layers or wherein the construct is formed as a homolaminate. Wherein the construct is in a sheet form and surgically implanted or in powder form is also not included.

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater

surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500  $\mu$  (page 17 line 14). Badylak ('637) also teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver

basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, one of ordinary skill in the art would have been motivated to use the method of the copending application for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20).

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badylak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct

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would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. The use of different forms such as multilayered, powder and sheet would have been obvious to include in the copending application because Badylak and Patel teach that these are suitable forms for the construct. The thickness of the layers of the construct would have been a matter of routine optimization depending on the thickness of the body wall in need of repair. One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, the combined teachings of the copending claims and Badylak and Patel render obvious Applicant's invention as claimed.

This is a provisional obviousness-type double patenting rejection.

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 9 of U.S. Patent No. 6,793,939 in view of Patel et al (US 5,955,110) and Badylak (WO 98/25637). Although the conflicting claims are not identical, they are not patentable distinct from each other because the patent is drawn to a method for inducing the formation of endogenous tissue at a site in need in a warm-blooded vertebrate comprising implanting a graft composition

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comprising an extracellular matrix consisting essentially of basement membrane of liver tissue of a warm blooded vertebrate in an amount effective to induce endogenous tissue growth at the site of administration. Wherein the basement membrane is fluidized and administered by injection and administered by surgically implanting and wherein the liver tissue is in sheets having a thickness of up to about 500  $\mu$  are also included.

The claims of the patent do not include wherein the body wall or abdominal wall is the site of repair or wherein the construct is multilayered, or wherein the construct is formed as a homolaminate. Wherein the construct is in a sheet form and surgically implanted or in powder form is also not included.

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of

a powder (page 4 line 22), sheet or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500  $\mu$  (page 17 line 14). Badylak ('637) also teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, one of ordinary skill in the art would have been motivated to use the method of the patent for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting

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endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20).

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badylak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. The use of different forms such as multilayered, powder and sheet would have been obvious to include in the copending application because Badylak and Patel teach that these are suitable forms for the construct. One of ordinary skill in the art would have had a reasonable expectation of

success because Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, the combined teachings of the patent claims and Badylak and Patel render obvious Applicant's invention as claimed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

Leon B Lankford, Jr  
Primary Examiner  
Art Unit 1651

Laura Schuberg